K042558 1/2



OCT 6 - 2004

*Equi-Flow™ Valve and Shunt System*
**510(k) SUMMARY**

**Submitter's name and address:**

Integra NeuroSciences Implants SA
2905 Route des Dolines
06921 Sophia Antipolis Cedex, France

**Contact person and telephone number:**

Valérie Gabert
Regulatory Affairs Specialist
Telephone: +33 (0)4 93 95 5626
Facsimile: +33 (0)4 93 65 4030

**Date summary was prepared:**

September 17, 2004

**Name of the device:**

| | |
|---|---|
| Proprietary Name: | Equi-Flow™ Valve and Shunt System |
| Common Name: | Hydrocephalus Shunt Systems and Components |
| Classification Name: | Central Nervous System Shunt and Components JXG |

**Substantial Equivalence:**

The Equi-Flow™ Valve and Shunt System is substantially equivalent in function and intended use to the currently marketed Equi-Flow™ Valve and Shunt System and Contour-Flex Valve and Shunt System 510K K033698 which have been cleared to market under Premarket Notifications 510(k)s K964386 and K971511.

**Intended use:**

The Equi-Flow™ Valve and Shunt System is indicated for use in the treatment of patients with hydrocephalus. The valve is a component of a system designed to shunt cerebrospinal fluid from the ventricles of the brain to an appropriate drainage site, such as the atrium of the heart or the peritoneal cavity.

The Equi-Flow™ Valve is indicated in patients where excessive reduction of intraventricular pressure or volume may be caused by a siphoning effect of hydrostatic pressure in the Distal Catheter.

**Device Description:**

The Integra NeuroSciences Equi-Flow™ Valve is a multi-function membrane valve incorporating a normally open Siphon Limiting Device, occluders, and integral tubing connectors. It is used in treatment of patients with hydrocephalus when shunting cerebrospinal fluid (CSF) from ventricles of the brain. It incorporates a central reservoir for pumping and injection, proximal and distal occluders, and a fully flexible profile.
The Siphon Limiting Device limits the siphon effect in the shunt system by closing when exposed to a negative Hydrostatic pressure (often caused by the patient sitting or standing)..

The Equi-Flow Valve incorporates a central reservoir for pumping and injection, proximal and distal occluders, and a fully flexible profile. The Equi-Flow Valve design includes a

flat silicone membrane, which provides resistance to CSF flow. The flat silicone membrane seats on a conical polypropylene base which is integral to the Siphon Limiting Device. This base is integral to a rigid outlet port. The design allows for accurate and precise regulation of CSF flow due to its structural integrity. The flat silicone membrane also prevents retrograde flow of CSF. The Equi-Flow valve is available in two sizes: Regular and Small. Both sizes are available in five pressure/flow characteristics ranges: Low/Low, Low, Low/Medium, Medium and High.

**Safety**

The Equi-Flow™ Valve and Shunt Systems are provided sterile and non-pyrogenic. The Equi-Flow™ Valve and Shunt Systems have been tested for pressure/flow, leakage, anti-reflux, catheter elongation and bending, and markings visual inspection.

**Conclusion**

The modified Equi-Flow™ Valve and Shunt System is substantially equivalent to the unmodified Equi-Flow Valve and Shunt System and Contour-Flex Valve and Shunt System. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

Integra NeuroSciences Implants, S.A.
c/o Ms. Judith E. O'Grady
Sr. Vice President, Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K042558
Trade/Device Name: Equi-Flow™ Valve and Shunt Systems
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: September 20, 2004
Received: September 21, 2004

Dear Ms. O'Grady:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K042558

**Device Name:**

Equi-Flow™ Valve and Shunt Systems

**Indications For Use:**

The Equi-Flow™ Valve and Shunt Systems are used in the treatment of patients with hydrocephalus. The device is designed to shunt cerebrospinal fluid from the ventricles of the brain to an appropriate drainage site, such as the atrium of the heart or the peritoneal cavity.

The Equi-Flow™ Valve is indicated in patients where excessive reduction of intraventricular pressure or volume may be caused by the siphoning effect of hydrostatic pressure in the Distal Catheter of the shunt system.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



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**510(k) Number** K042558